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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,950	11/05/2001	Rainer Goldau	2565/86	9979
26646	7590	08/18/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 08/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,950

Applicant(s)

GOLDAU ET AL

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 8-11, 24 and 25 is/are allowed.
6) ☒ Claim(s) 1-7, 12-23 and 26-31 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 12-23, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,384 to Goux et al in view of US 6,258,027 to Sternby et al. Goux discloses a method of determining a parameter of extracorporeal blood treatment that includes the steps claimed by applicant. In particular, Goux discloses that the blood flows through one side of the dialyzer loop, with treatment fluid through the second side of the loop. While the treatment fluid flows through the treatment side of the loop, the operator varies the value of a component in the stream of treatment fluid upstream of the dialyzer, measuring the value of the component downstream of the dialyzer, and calculating the parameter indicative of the treatment. Such a calculation may include a calculation of a substance in the patient's blood. See columns 2-4. The system comprises conductivity sensors 23 and 25 both upstream and downstream of the dialyzer for taking measurements, a syringe driver for altering the characteristic of the dialyzing fluid, and a computing and control unit 30. Goux fails to disclose that the Kt/V measurement obtained in his method can be used to extrapolate V, the distribution volume of a substance in the patient's blood. However, Sternby discloses a method whereby measurements are taken from the blood side and dialysate side in an

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extracorporeal treatment, and the values extrapolated to determine V , the distribution volume of a substance in the blood, an important clinical measurement to determine the parameters of patient treatment (see columns 17-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of taking measurements disclosed by Goux and using those measurements to extrapolate the distribution volume of a substance in the patient blood in order to determine and adjust patient treatment, as taught by Sternby.

Allowable Subject Matter

3. Claims 8-11, 24, and 25 are allowed.
4. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a method for determining a distribution volume of a blood component using the specific time and characteristic manipulations as claimed by applicant, along with the other steps and limitations of the claims.

Response to Arguments

5. Applicant's arguments filed 14 June 2005 have been fully considered but they are not persuasive. Applicant argues that Goux fails to disclose how to calculate the volume of distribution of urea in the body and Sternby does not cure that deficiency since it requires calculation of another variable in the equation at the start of the procedure, not after an alteration of a characteristic of the dialyzing fluid. As argued in the Final Rejection, the Sternby reference is used demonstrate that given the value of other

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variables in the equation Kt/v , it would have been obvious to one of ordinary skill in the art at the time of invention to complete the algebraic equation to determine the volume of distribution of urea in the body, as claimed by applicant. The timing of Sternby's calculations or the use of a different formula does not affect the teaching of Sternby that, given the other variables in an equation, determining the value of the desired variable is an obvious manipulation of an algebraic equation. Therefore, the references are properly combinable to show that it would have been obvious to one of ordinary skill in the art at the time of invention to use the apparatus and method disclosed by Goux to determine the value of urea distribution in the body given the values measured by the sensors in the apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
10 August 2005

Patricia Bianco
PATRICIA BIANCO
PRIMARY EXAMINER